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10/597,677	04/19/2007	Robert Gordon Hood	9931-010US	4798

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EXAMINER	
TANNER, JOCELIN C	
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3731	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,677	HOOD ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 26 November 2008. Claims 1-4 and 17-32 are now pending.

Response to Amendment

1. The Declaration under 37 CFR 1.132 filed 26 November 2008 is insufficient to overcome the rejection of claims 1-4, 17-25 and 27-32 based upon a specific reference applied under 35 U.S.C. 103 citing Houston et al. (US PGPub No. 2003/0139807) in view of Falotico et al. (US Patent No. 7,195,640) as set forth in the last Office action because: the Applicant contends that neither document provides any suggestion of the technical advantage of a spiral stent eluting more drug than a stent without a spiral formation. However, the Declaration is unclear because in Appendix 1, the spiral stent accumulates a heavier coating than the control, which may be due to the spiral. The heavier coating may be the result of the spiral coating having greater elution of the drug since there is more drug to elute and the drug is located within a spiral. Therefore, the results may not have been expected but would be obvious due to the heavier coating.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, 3, 4, 20-21, 24, 25 and 32 rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (US Patent No. 6,071,305).**

4. Regarding claim **1**, Brown et al. discloses a vascular implant (11) having a blood-contacting surface and a helical formation (12) on the blood-contacting surface having the capability of inducing helical flow of blood flowing past the helical formation and a drug being releasably associated with the helical formation (column 5, lines 36-44, 55, 65-67, Figs. 2, 2A, 4).

5. Regarding claim **3**, Brown et al. discloses a drug coated onto the surface of the helical formation (12) (column 6, lines 5-20, Figs, 2, 2a).

6. Regarding claim **4**, Brown et al. discloses a helical formation (12) formed of polymer (column 7, lines 19-22).

7. Regarding claim **20**, Brown et al. discloses anti-platelet function drugs (column 5, lines 6-26).

8. Regarding claim **21**, Brown et al. discloses a vascular implant as being a stent (column 5, lines 37-38).

9. Regarding claim **24**, Brown et al. discloses the drug as being releasably associated with the blood-contacting surface of the vascular implant (column 6, lines 5-15).

10. Regarding claim **25**, Brown et al. discloses more than one drug provided by the helical formation (column 3, lines 43-45).

11. Regarding claim **32**, Brown et al. discloses a groove (20) within the helical formation (12) (Fig. 2A).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. **Claims 1-4, 17-25, and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (US PGPub No. 2003/0139807) in view of Falotico et al (US Patent No. 7,195,640).**

14. Regarding claim **1**, Houston et al. discloses a stent or "drug delivery device" including a vascular implant [0011], i.e. stent, stent graft or graft, having a blood-contacting surface and a helical formation on the blood contacting surface (FIG. 1, element #2), the helical formation being capable of inducing helical flow of blood flowing past [0042]. However, Houston et al. fails to disclose a drug.

Falotico et al. teaches a coated medical device or "drug delivery device" that may be coated with any number of therapeutic drugs, agents or compounds (column 10, lines 3-5).

Because Houston et al. and Falotico et al. teach known devices, i.e. stents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the helical stent of Houston et al. with the therapeutic and pharmaceutical drug coating, as taught by Falotico et al., for the predictable result of effectively maintaining vessel patency with treatment while reducing local turbulence in blood flow and reduced potential toxicity of drugs.

15. Regarding claim **2**, the combination of Houston and Falotico discloses all of the limitations. Further, Falotico et al. teaches a stent or "drug delivery device" formed by the mixing of a polymer and rapamycin, an antibiotic used to treat restenosis, by directly incorporating rapamycin into a polymeric matrix wherein the rapamycin elutes from the polymeric matrix over time into the surrounding tissue (column 14, lines 1-4 and column 18, lines 50-59).

16. Regarding claim **3**, Falotico et al. teaches coating the inner and outer surface of the stent with drug/drug combinations wherein the inner surface contains the helical formation (column 12, lines 53-55).

17. Regarding claim **4**, Houston et al. discloses a helical formation made from polyurethane, a polymer [0039].

18. Regarding claim **17**, Houston et al. discloses a helical formation made from polymer foam [0050].

19. Regarding claim **18**, Houston et al. discloses a helical formation made from polyurethane [0039].

20. Regarding claim **19**, Falotico et al. teaches a drug that is bound onto the cellular structure of the polymer through crosslinking wherein the pharmaceutical agents are bonded to the atoms and chains of the polymers of the coatings and films (column 19, lines 65-67).

21. Regarding claim **20**, Falotico et al. teaches therapeutic and pharmaceutical coatings of antiplatelet agents, anticoagulants and fibrinolytic agents (column 10, lines

14, 29-30 and column 18, lines 29-30) wherein the coatings can be layered to control release of different agents placed in different layers (column 18, lines 2-4).

22. Regarding claim **21**, Houston et al. discloses a vascular implant that is a stent, stent graft and a graft [0011].

23. Regarding claim **22**, Houston et al. discloses a membrane or "sleeve" within the stent that is made of flexible material and attached to the body of the stent [0046].

24. Regarding claim **23**, Houston et al. discloses the sleeve being formed of PTFE material [0046].

25. Regarding claims **24 and 25**, Falotico et al. teaches a drug that is releasably associated with the blood-contacting surface of the vascular implant and helical formation wherein the coatings containing therapeutic agents are applied into and onto the stent by way of spraying, spinning or dipping (column 14, lines 29-31) and the drug is released through diffusion dependent on the desired release profile (column 19, lines 29-36).

26. Regarding claim **27**, Houston et al. discloses a helical formation having at least one fin (FIG. 3, element #6 and #7, [0048]).

27. Regarding claim **28**, Houston et al. discloses a fin having the shape of a right-angle triangle in cross-section (FIG. 5, [0048]).

28. Regarding claim **29**, Houston et al. discloses a fin having the shape of an isosceles triangle in cross-section (FIG. 6, [0049]).

29. Regarding claim **30**, Houston et al. discloses a fin having the shape of a bell in cross-section (FIG. 7).

30. Regarding claim **31**, Houston et al. discloses a fin having the shape of an asymmetric bell in cross-section (FIG.7).

31. Regarding claim **32**, Houston et al. discloses a helical formation having a groove between the two extending fins that extend along the length of the longitudinally extending member of the formation (FIGS. 1 and 2).

32. **Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (US PGPub No. 2003/0139807) in view of Falotico et al (US Patent No. 7,195,640), further in view of Houston et al (EP 1254645A1).**

33. Regarding claim **26**, the combination of Houston et al. and Falotico et al. discloses all of the limitations. However, the combination of Houston et al. and Falotico et al. fails to disclose an angle of the helical formation between 8° and 20°.

Houston et al. teaches a helical formation having a helix angle between 5° and 50°, preferably about 16°, to reduce turbulence [0013].

Because the combination of Houston et al. and Falotico et al. and Houston et al. teach known devices, i.e. helical formations to reduce turbulent flow, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the helical formation of the combination of Houston et al. and Falotico et al. with the helix angle of 16° (between 8° and 20°), as taught by Houston et al, for the predictable result of inducing helical flow to eliminate turbulence.

34. **Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305) in view of Kaplan (US Patent No. 5,342,348).**

35. Regarding claim **2**, Brown et al. discloses all of the limitations previously discussed except for a drug mixed into the material from which the helical formation was made.

Kaplan teaches a stent including an interwoven filament having a bioactive substance absorbed or impregnated therein (column 3, lines 20-31, Fig. 1A).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have mixed the drug into the material of the helical formation of the device of Brown et al., as taught by Kaplan, to deliver therapeutic substances to selected locations within a vascular system.

36. **Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305) in view of Dutta et al. (US Patent No. 6,702,849).**

37. Regarding claim **17**, Brown et al. discloses all of the limitations previously discussed except for a helical formation formed of a polymer foam.

Dutta et al. teaches a device formed of open-celled microcellular polymeric foams having a porosity that can be modified to be adapted for delivering therapeutic drugs (column 2, lines 55-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the helical formation of the device of Brown et al., as taught by Dutta et al., to provide control of pores within material through which therapeutic drugs are delivered.

38. Regarding claim **18**, Brown et al. discloses a the helical formation (12) being formed of polyamide (column 7, lines 20-21).

39. **Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305) in view of in view of Dutta et al. (US Patent No. 6,702,849), as applied to claim 17 above, and further in view of Davila et al. (US PGPub No. 2002/0111590A1).**

40. Regarding claim **19**, Brown et al. discloses all of the limitations previously discussed except for a drug bound onto the cellular structure of the polymer.

Davila et al. teaches a polymeric coatings for medical devices wherein entrainment of polymer chains into the drug-containing matrix is promoted [0186].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have bound a drug onto the cellular structure of the polymer of the device of Brown et al., as taught by Davila et al., to increase the adhesion strength between the polymer and drug-containing matrix.

41. **Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305) in view of Banas et al. (US Patent No. 5,749,880).**

42. Regarding claim **22**, Brown et al. discloses all of the limitations previously discussed except for a sleeve positioned around or within the stent.

Banas et al. teaches an encapsulated stent (10) having tubular members or sleeves (24, 26) on the interior and exterior surfaces of the stent (column 12, lines 16-20, 44-47, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a sleeve to the exterior or interior surface of the stent of Brown et al., as taught by Banas et al., to reduce thrombogenicity by providing ePTFE encapsulation covering the luminal and abluminal surfaces.

43. Regarding claim **23**, Banas et al. teaches an ePTFE sleeve (24, 26) (column 12, lines 44-47, Fig. 2).

44. **Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305).**

45. Regarding claim 26, Brown et al. discloses the claimed invention except for a helical formation having a helix angle between 8° and 20°. It would have been an obvious matter of design choice to have provided a helical formation having a helix angle between 8° and 20° since applicant has not disclosed that an angle between 8° and 20° solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a helix angle appropriate for the size of the stent used for the particular application.

46. **Claims 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (US Patent No. 6,071,305) in view of Stinson (US PGPub No. 2004/0044397A1).**

47. Regarding claims **27**, Brown et al. discloses all of the limitations previously discussed except for at least one fin.

Stinson teaches fibers (26) having various cross-sectional configurations including polygonal shaped configurations having 3 or more sides [0060].

Therefore, it would have been obvious to one of ordinary skill in the art to have provided the helical formation of Brown et al. with a fine, as taught by Stinson, to have provided an abrasive surface to the helical formation.

48. Regarding claims **28-31**, Brown et al. discloses the claimed invention except for at least one fin except for a right-angle triangle, isosceles triangle and an asymmetric bell shaped fin. It would have been an obvious matter of design choice to have provided multiple shaped fins, since applicant has not disclosed that having multiple shaped fin configurations solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a helical formation having a substantially round fin.

Response to Arguments

49. Applicant's arguments filed 26 November 2008 have been fully considered but they are not persuasive. The Applicant contends that the references fail to disclose the dynamics of drug delivery, how the stent might be adapted in order to hold more of the drug, and a helical feature on the outer surface of the stent. However, the combination of Houston et al. and Falotico et al. were not combined for the same reasons as the instant application. It was well known in the art to provide an interior or exterior drug coating to a stent to minimize the reaction to the introduction of a device or to treat various vascular diseases since the interior and exterior surfaces of a stent come into

contact with blood. Therefore, it would have been obvious to have more drug collect within a groove of a stent, thus resulting in a longer eluting process.

50. The Examiner has submitted an additional new ground of rejection above.

Conclusion

51. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3/13/2009
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